**MENTHOL- menthol cream**
**Jag Alliance, LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**73143-010-03**

## ACTIVE INGREDIENT

Menthol 10%

## PURPOSE

Topical Analgesic

## USES

Aid for temporary local relief of minor pain in muscles or joints.

## WARNINGS

- For external use only.
- Avoid contact with eyes.
- If symptoms persist for more than seven days, discontinue use and consult a physician.

## IF PREGNANT OR BREAST – FEEDING:

- Ask a health professional before use.

## KEEP OUT OF REACH OF CHILDEN:

- If swallowed, get medical help or contact a Poison Control Center right away.
- Emergency Number: 1-800-222-1222

## DIRECTIONS:

Adults and children two-years of age or older:

- Apply to affected area not more than three to four times daily.
- Children under two-years of age: consult a physician.

## Additional Information

Store at room temperature.

## Inactive ingredients

Aqua, Caprylic/Capric Triglyceride, Alcohol Denat., Stearic Acid, Cetyl Alcohol, Dimethicone, Glyceryl Stearate, Caprylyl Glycol, Phenoxyethanol, Hexylene Glycol, Helianthus Annuus Seed Oil, Butyrospermum Parkii Butter, Cannabis Sativa Seed Oil, Glycereth-26, Persea Gratissima Oil, Stearyl Alcohol, Sodium Polyacrylate, Aloe Barbadensis Leaf Extract, Glycerin, Boswellia Serrata Extract, Melaleuca Alternifolia Leaf Oil, Mentha Arvensis Herb Oil, Arnica Montana Flower Extract.


# MENTHOL

menthol cream

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:73143-010 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **MENTHOL, UNSPECIFIED FORM** (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A) | MENTHOL, UNSPECIFIED FORM | 10 g in 100 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **GLYCERETH-26** (UNII: NNE56F2N14) | |
| **STEARYL ALCOHOL** (UNII: 2KR89I4H1Y) | |
| **SODIUM POLYACRYLATE (8000 MW)** (UNII: 285CYO341L) | |
| **MENTHA ARVENSIS FLOWER OIL** (UNII: Q129Z1W6Y2) | |
| **ARNICA MONTANA FLOWER WATER** (UNII: U7L2JP51PR) | |
| **HEXYLENE GLYCOL** (UNII: KEH0A3F75J) | |
| **CAPRYLYL GLYCOL** (UNII: 00YIU5438U) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **HELIANTHUS ANNUUS FLOWERING TOP** (UNII: BKJ0J3D1BP) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **CANNABIS SATIVA SEED OIL** (UNII: 69VJ1LPN1S) | |

| | |
|---|---|
| **MELALEUCA ALTERNIFOLIA FLOWERING TOP** (UNII: 5AZ4S6N66F) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **DIMETHICONE 1000** (UNII: MCU2324216) | |
| **GLYCERYL STEARATE SE** (UNII: FCZ5MH785I) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:73143-010-03 | 96 g in 1 CAN; Type 0: Not a Combination Product | 07/18/2019 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part348 | 07/18/2019 | |

## Labeler - Jag Alliance, LLC (081456767)

## Registrant - Chemco Corporation (032495954)

Revised: 12/2020 Jag Alliance, LLC